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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/691,405	10/17/2000	Steven R. Binder	2558B-063700US	3942

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EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 08/06/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/691,405

Applicant(s)

BINDER ET AL.

Examiner

Marianne Allen

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Information Disclosure Statement***

Applicant is encouraged to file an information disclosure statement.

### ***Claim Rejections - 35 USC § 112***

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to a method for the identification of a systemic autoimmune disease by analyzing a biological sample, comparing this to a library of reference datasets, and applying pattern recognition means to produce a decision indicating which disease the subject is suffering from. Dependent claim 2 requires diagnosis of multiple autoimmune diseases.

The specification details the difficulties in diagnosing autoimmune disorders based upon transient symptoms, overlapping symptoms, variations in normal antibody levels, and so forth.

The specification lists a variety of autoimmune diseases and lists a variety of antigens (see pages 7-8). However, the specification does not associate any antigen (or autoantibody) with any particular disease with respect to presence (or absence) and amounts as implied by the claim. Nor does the specification disclose how discrimination between different autoimmune diseases, particularly with those that involve overlapping autoantibodies, is to be implemented. To the degree that any of this may be remedied by Peter et al. (referenced on page 7 of the specification), this is an improper incorporation by reference of essential material.

The specification does not disclose any particular pattern recognition means beyond naming some types of statistical analysis that may be used in such a means. That is, "principal component analysis" can be used in pattern recognition but it does not provide a pattern recognition means in and of itself. Such pattern recognition methods must be developed, certain assumptions made as to what data will be used, what specific attributes will be analyzed, how they will be analyzed, which algorithms to use, what the composition of the training set and test sets will be and so forth. They must be tested, evaluated, and usually refined. The specification does not exemplify any implementation of the claimed methods and provides no specific guidance for doing so. Note that these are not, for example, complete commercially available pattern recognition programs or systems where applicant must merely supply a specified type of data for analysis.

Applicant's specification is an invitation to experiment to develop the claimed method. It is noted that claims 1-6 and 9-16 require that one of ordinary skill in the art determine which autoantibodies are to be analyzed. Note that the specification implies that the reference sets required by the claims do not exist and must be developed for all of the autoimmune diseases and autoantibodies.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what symptoms the test subject of must possess to meet the limitation of being "suspected of suffering from an otherwise unidentified systemic autoimmune disease" selected from the named group.

As written, claim 2 is confusing. It requires foreknowledge that the test subject is suffering from two autoimmune diseases, yet the preamble of claim 1 requires that the subject be suspected of suffering from an unidentified systemic autoimmune disease.

Claim 3 is confusing in referring to the listed statistical analysis techniques as pattern recognition means. They are not pattern recognition means. See page 5, lines 6-13, of the specification.

Claims 7 and 8 lack a terminal period (".") and should have "and" or "or" separating the last two members of the lists of antigens.

Claim 11 does not further limit the subject matter of claim 1. The "statistically derived decision" of claim 1 implies a confidence level. Note that claim 11 does not require a particular confidence level.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Grus et al. (*Electrophoresis*, 18:1120-1125, 1997).

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Grus et al. discloses screening sera for autoantibodies with Western blots. The resulting blots are analyzed with a pattern recognition algorithm by an artificial neural network to using a neural network to classify a patient's autoimmune disease. The trained neural network was used to predict the correct diagnostic group for unknown blots. (See at least abstract, figures, and sections on software development, neural networks, and results.)

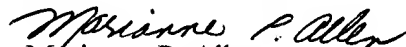
### *Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Friday, 7:00 am - 1:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Marianne P. Allen  
Primary Examiner  
Art Unit 1631

mpa  
August 1, 2002